DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Institute of Mental Health
6001 Executive Boulevard
Bethesda, Maryland 20892

April 15, 2003

Dear Sir/Madam:

The National Institute of Mental Health (NIMH) invites you to submit a proposal in accordance with the requirements and instructions of Request for Proposals (RFP) No. NIMH-03-DM-0003 entitled "**Treatment Units for Research on Neurocognition and Schizophrenia (TURNS)**." Proposals are being solicited under Full and Open Competitive procedures.

It is expected that one cost-reimbursement contract will be awarded on or before September 30, 2003 with a base period of four (4) years.

Special attention should be directed to the technical proposal instructions and business proposal instructions contained in **Attachment 4.**

The documents included with this electronic RFP package are as follows:

I. Streamlined RFP:
   - A. Statement of Work (SOW) **(Attachment 1)**
   - B. Deliverables and Reporting Requirements **(Attachment 2)**
   - C. Evaluation Factors for Award **(Attachment 3)**

II. Standard RFP Instructions and Conditions and Notice to Offerors **(Attachment 4)**
III. Applicable RFP References/Forms/Web links **(Attachment 5)**
IV. Proposal Intent Response Sheet **(Attachment 6)**
V. Past Performance Questionnaire **(Attachment 7)**

The attachments listed above represent all the necessary information required for the submission of a proposal for this acquisition.

An official authorized to contractually bind your organization must sign your proposal. One (1) original and ten (10) copies of your technical proposal, and one (1) original and seven (7) copies of your Business/Cost Proposal, must be received by the Contracting Officer NO LATER THAN **1:00 p.m.**, **local prevailing time, on May 30, 2003**, at the following address:

If hand delivered or using overnight delivery service:	If using U.S. Postal Service:
Attn: Suzanne Stinson Contracting Officer National Institute of Mental Health Contract Management Branch 6001 Executive Blvd., Rm. 8153 Rockville, MD **20852**-9603	Attn: Suzanne Stinson Contracting Officer National Institute of Mental Health Contract Management Branch 6001 Executive Blvd., Rm. 8153 (MSC 9661) Bethesda, MD **20892**-9603

Your attention is further directed to the "Proposal Intent Response Sheet" contained in **Attachment 6**. Please complete this form and return it to this office or notify me at the following Internet address: ss704b@nih.gov on or before May 2, 2003. This will allow us to expedite preparations for the peer review of proposals.

IF THERE ARE ANY AMENDMENTS TO THIS SOLICITATION, THEY WILL BE AVAILABLE ON THE INTERNET at FedBizOpps at http://www.fedbizopps.gov and/or the NIMH HOME PAGE AT: http://www.nimh.nih.gov/grants/indexcon.htm . It is the offerors responsibility to monitor these websites for possible solicitation amendments.

This RFP does not commit the Government to pay any costs for the preparation and submission of a proposal. It is also brought to your attention that the Contracting Officer (CO) is the only individual who can legally commit the Government to expenditure of public funds in connection with this proposed acquisition.

Any discussion of this RFP with any individual(s) outside the Contracts Management Branch, NIMH, may result in disqualification of the offeror and rejection of any proposal submitted.

Questions concerning any areas of uncertainty, which in your opinion require clarification or correction on the part of NIMH, must be furnished in writing to Suzanne Stinson, and marked "Offeror's Questions, RFP No. NIMH-03-DM-0003". You are requested to submit (preferably via "e-mail") your questions to Suzanne Stinson (ss704b@nih.gov). It would be appreciated if you questions were received in the contracting office on or before May 2, 2003, to allow a reply to reach all prospective offerors before submission of their proposals.

Sincerely,
/s/
Suzanne Stinson
Contracting Officer
Contracts Management Branch, ORM
National Institute of Mental Health, NIH

Attachments: 1-7

ATTACHMENT 1
STATEMENT OF WORK
RFP No. NIMH-03-DM-0003

Title: Treatment Units for Research on Neurocognition and Schizophrenia (TURNS)

A. Introduction

Despite treatment with the best current pharmacological agents, many patients with schizophrenia experience substantial long-term impairment and disability. Recent cross-sectional and longitudinal studies suggest that cognitive impairment, rather than "positive" symptoms (delusions and hallucinations) are the major determinant of short- and long-term functional outcome in this disorder. Advances in understanding the systems-level neurobiology and neuropsychopharmacology of cognition are yielding new hypotheses to inform therapeutic approaches. Treatment development, however, has been hampered by a lack of scientific consensus regarding both the key cognitive impairments to be targeted and the selection of reliable and valid measurement tools to assess cognition as a dependent variable in treatment trials. Given these limitations, Food and Drug Administration (FDA) processes and precedents have not yet evolved sufficiently to provide clear guidance with respect to methods and measures required to establish the safety and efficacy of putatively pro-cognitive agents in schizophrenia.

To overcome this barrier to treatment improvements for schizophrenia, NIMH has taken steps to achieve broad academic and industry consensus regarding the nature of cognitive impairments in schizophrenia and how they might best be assessed. A current NIMH contract with UCLA, Measurement and Treatment Development on Cognition in Schizophrenia(MATRICS), see www.matrics.ucla.edu, will convene consensus oriented meetings to: 1) develop a comprehensive assessment tool to measure cognitive functioning in people with schizophrenia, 2) review preclinical models of neurocognition to identify potential molecular targets for therapeutic agents, 3) develop models for industry/government collaboration in the identification and testing of compounds targeting cognition and schizophrenia, and 4) identify potential lead compounds for this indication.

Drawing on the expertise of a wide range of academic and industry scientists, MATRICS contract participants are currently developing a neurocognition assessment tool using the RAND appropriateness method. By March 2005, this instrument will be finalized and its psychometric properties, including test- retest reliability and predictive validity, will be characterized. In addition, the MATRICS contract will convene a joint FDA/NIMH meeting (April 2004) to review measurement and methodological issues relevant to assessing cognition in schizophrenia as an endpoint in clinical trials.

The purpose of this contract is to establish a network of Treatment Units for Research on Neurocognition and Schizophrenia (TURNS) that will utilize the scientific opportunity created by new insights into the neurobiology of attention, working memory, and other fundamental cognitive processes, to identify and test potential therapeutic agents targeting cognitive deficits in schizophrenia. These treatment units will engage in a range of scientific activities in order to:

1) Further define and specify critical aspects of cognition in schizophrenia as potential treatment targets;

2) Identify and select promising compounds and conduct proof of concept and/or phase II clinical trials.

3) Define optimal experimental designs to evaluate the efficacy of primary and augmentation strategies to enhance cognition in schizophrenia;

4) Identify and develop opportunities for industry/academia/government collaboration in testing compounds of potential utility in alleviating cognitive deficits in schizophrenia;

5) Promote broad academic and industry uptake of standardized methods and measures to accelerate testing and regulatory approval of new compounds targeting cognitive deficits in schizophrenia;

6) Broadly and equitably disseminate state-of-the art measurement tools and methodological strategies to evaluate the efficacy of treatments for cognitive deficits in schizophrenia.

B. Services to be Performed

Independently, and not as an agent of the Government, the Contractor(s) shall furnish the necessary labor, materials, supplies, equipment, and services and perform the work set forth below. The duration of the contract shall be for forty - eight (48) months and shall consist of three stages.

C. Purpose

It is anticipated that the Treatment Units for Research on Neurocognition and Schizophrenia (TURNS) will become national resources where studies of the safety and efficacy of novel compounds targeting cognition in schizophrenia can be conducted in a prompt and cost effective manner. This will be accomplished by building on existing research resources at the host institutions and by combining the necessary expertise in clinical pharmacology and neuropsychology. The TURNS will work as a network of research units/sites, identify promising potential procognitive therapeutic agents, and conduct high priority clinical studies focused on enhancing neurocognition in schizophrenia including (but not limited to) general safety profile, drug-drug interactions, efficacy (particularly early proof of concept), dose ranges, dose regimen, pharmacokinetics, and effect on other dimensions of symptomatic and behavioral disturbance in schizophrenia. In addition, the TURNS will promote the validation of specific measures of cognition in schizophrenia for use as endpoints in clinical trials and refine methodological approaches for determining the efficacy of compounds for this indication. One of the TURNS ("a leader among peers") will function as a Coordinating Center (Contractor) for the entire project. This lead TURNS shall assemble a team of senior researchers who provide intellectual leadership in Neuropharmacology of Cognition in Schizophrenia. The lead TURNS shall also motivate and lead the contract-related activities performed at each TURNS.

D. Objectives

- To establish TURNS where clinical studies on the safety, efficacy, pharmacokinetics and pharmacodynamics of new agents for the treatment of cognitive deficits in schizophrenia can be investigated.

- To conduct a minimum of 2 NIMH-supported studies at each TURNS (of which one shall be a clinical efficacy trial and the other a pharmacokinetic and/or pharmacodynamic dose finding study or a second clinical efficacy and tolerability study). In addition, by the end of the contract period, it is expected that each TURNS site will have obtained other Federal, Foundation, and/or pharmaceutical industry funds to conduct a third clinical efficacy trial.

- To spur the conduct of other clinical trials and human clinical studies related to neurocognitive deficits in schizophrenia to be funded through mechanisms other than this contract (i.e., investigator-initiated grants from federal agencies, private foundations, and/or pharmaceutical companies).

E. Stage One

During the first 9 months of the contract, the lead TURNS (Coordinating Center), shall:

I. Establish the infrastructure of the TURNS, including its locations, staffing, and liaisons with collaborating parties (see Addendum A). Each TURNS should at a minimum have the demonstrated ability to recruit patients with schizophrenia into clinical trials and complete project recruitment within projected timeframes, have sufficient expertise in neuropsychology to train raters to reliably administer neuropsychiatric test batteries as a repeated measure in clinical trials, and have sufficient experience and expertise in neuropharmacology to contribute to the identification, acquisition, and evaluation of potential therapeutic compounds for the treatment of cognitive deficits in schizophrenia. Each TURNS shall be able to:

- Participate with the other TURNS and NIMH staff in preparing for collaborative clinical trials of pharmacological agents targeting neurocognitive deficits in adults with schizophrenia, including identification, evaluation, and prioritization of potential lead compounds, as determined by the Government Project Officer (GPO) and the TURNS Network Steering Committee (TNSC) (see E. 3)

- Provide a setting where studies on various aspects of the safety, efficacy, pharmacodynamics, pharmacokinetics, and mechanism of action of putatively pro-cognitive agents can be conducted in adults with schizophrenia, using both funds awarded directly through this contract and ultimately through funds secured from sources other then this contract (e.g., investigator-initiated grants from federal agencies, private foundations, and/or funding from pharmaceutical companies)

- Provide an environment where clinical researchers and patient-oriented research trainees can gain supervised expertise in psychopharmacology research, especially focused on the treatment of patients suffering from schizophrenia and other psychotic disorders.

To this end, during the first 9 months, the Coordinating Center shall, at a minimum: 1) identify and occupy appropriate space; 2) identify and hire staff; 3) finalize the selection of TURNS units, and award subcontracts; 4) finalize the research protocols (see Addendum B) of at least one the studies to be conducted by the TURNS; 5) obtain Institutional Review Board (IRB) approvals for the protocol; 6) specify procedures for monitoring and reporting adverse events and assuring appropriate data management, that can meet the high standards required by FDA for clinical trials; 7) prepare consent documents, procedural manuals and other documentation related to the performance of the trial; 8) establish a steering committee and its rules of operation; 9) arrange for/procure required equipment, supplies and other study material (e.g., medications, assessment instruments) to conduct clinical studies; 10) establish a TURNS web site; and 11) perform a wide range of activities in preparation of the performance of the clinical trials (see Addendum C).

II. The Coordinating Center shall be responsible for; (1) overall monitoring of individual TURNS units; (2) designing, developing, overseeing, monitoring and coordinating the data management and analysis

activities of the TURNS (see Addendum D); (3) removal and replacement of non-performing TURNS units; (4) organizing and coordinating the project steering committee; (5) ensuring clinical trials initiated by the network are completed in a timely manner and within budgeted costs, and 6) ensuring that expertise exists within the TURNS to accomplish experimental design and biostatistics, subject recruitment, protocol adherence, clinical ratings, neuropsychological test administration, human subjects protection, and all other research and clinical activities associated with TURNS protocols.

1. In addition to meeting the conditions specified under Addendum B, each TURNS (including the lead TURNS functioning as the Coordinating Center) shall consist of the following components:

a. Principal Investigator: The Principal Investigator (PI) of the unit shall be an established researcher in schizophrenia psychopharmacology, holding independent peer-reviewed grants and/or contract support, and actively publishing in the field. The PI shall be responsible for developing and maintaining the unit as an institutional and national resource. It is expected that the PI at each TURNS will devote at least 15% of her/his full time availability to the contract. The PI will select and coordinate a team of investigators and support staff capable of conducting research on the safety, efficacy, pharmacokinetics and pharmacodynamics of psychotropic medications in adults with schizophrenia. Required expertise in adult psychiatry (especially schizophrenia and psychotic disorders), clinical pharmacology, and toxicology shall be available within the unit's research team or from external consultants. The PI shall name the Chief Neuropsychologist and other members of the unit's staff, shall actively conduct research in the unit, and lead other unit activities including identification, evaluation and prioritization of lead compounds. Further, as one of the objectives of this contract is to spur the conduct of other clinical trials and human clinical studies related to neurocognitive deficits in schizophrenia, the PI shall actively seek financial support from various sources, such as private foundations and pharmaceutical companies. The PI shall assist other TURNS investigators in organizing and conducting network research protocols. The PI shall attend the meetings of the network steering committee and participate in its deliberations. The PI shall hold final authority and responsibility for the scientific aspects of the research activities of the unit, even though responsibility for the clinical care of the research subjects may be in the hands of other investigators or treating physicians. If the PI is a fully licensed physician the other leader of the study can be a non-physician holding a Ph.D. or Pharm.D. degree, with established expertise in psychopharmacology of schizophrenia and neuropsychological assessment in a clinical trial environment.

b. Chief Neuropsychologist: At a minimum, the Chief Neuropsychologist should be an established researcher with expertise in clinical trials and neuropsychological assessment in schizophrenia, preferably holding peer reviewed grants or contracts and active in presenting at national meetings and publishing in peer-reviewed journals. With the PI (if not the PI), the Chief Neuropsychologist will provide scientific oversight and direction for the treatment unit and will be responsible for insuring training and supervision of clinical staff who administer cognitive tests as primary endpoints in clinical trials of putatively pro-cognitive agents in schizophrenia

c. Clinical Pharmacologist: At a minimum, the clinical pharmacologist (who may be the PI) shall be a fully licensed physician able to take responsibility for the clinical aspects of TURNS research.

d. Other Unit Staff: The unit shall have staff, or access to staff, to accomplish all the planned research activities, including nursing, pharmacy, and data management.

Note: A staff loading chart for the Coordinating Center and each TURNS shall be included with the technical proposal.

e. Clinical Facility: The TURNS shall have a designated physical site where the clinical research is to be performed. To allow optimal opportunities for conducting various research protocols, each TURNS shall have both an inpatient and outpatient capability. The TURNS shall have the support of a full range of services necessary to conduct research studies, including a pharmacy experienced in the preparation of materials for randomized clinical trials. The TURNS shall have access to a laboratory where analyses and assays necessary for research in psychopharmacology can be conducted.

f. Monitoring of Safety: Each unit shall utilize standard procedures to identify, score, and report in an effective and timely manner all possible and actual adverse events. A data safety monitoring board (DSMB) should be operational for each multisite TURNS clinical trial, unless the GPO, in consultation with the steering committee, agrees on a case-by-case basis that it is not necessary. In the case of protocols funded by NIMH, the GPO shall concur in the format and membership of the DSMB. In the case of local protocols or protocols funded through sources other than this contract, the DSMB shall be appointed and coordinated by the Contractor (i.e., the unit's PI). A DSMB shall be in place prior to recruiting or enrolling any patients for a multisite protocol funded by NIMH. (For further information on DSMB requirements, see Attachment 4, item G, Technical Proposal Instructions, item 15).

g. Data Management: Each TURNS shall utilize specific procedures for data collection, quality assurance process, storage, transfer, and analysis that meet good clinical trial practice criteria. The system shall ensure adequate protection of confidentiality of the research subjects. Because some of the studies funded under this contract are likely to be multisite studies, i.e. ,conducted at more than one research unit, the data management system shall ensure that data from the various sites can be appropriately merged and analyzed.

h. Local Advisory Committee (LAC): Each TURNS will have a LAC that will evaluate protocols to be conducted at that unit for scientific merit and feasibility, and recommend priorities for the use of the TURNS resources. The committee should also examine the qualifications of candidates for the associate clinical pharmacologist and other positions, and report their recommendations to the PI. The LAC shall be chaired by the unit's PI and include 3-5 other members appointed by the PI for defined terms. Members should incorporate individuals with pharmacologic expertise and and at least one consumer or family member of a person with schizophrenia. LAC advice shall be especially important on protocols and activities that are conducted only at that unit.

2. Publication Committee: This committee shall be responsible for reviewing all manuscripts developed using data under this contract. The committee will play an active role in coordinating the dissemination of results to the scientific and lay community, including but not limited to, printed material, electronic dissemination, and if applicable, website development. Publication Committee members shall include, at a minimum, the Coordinating Center PI and representation from other TURNS. The GPO shall serve as an ex officio member of the committee, and shall have the opportunity to comment on all publications prior to their approval by the committee and submission for publication.

3. TURNS Network Steering Committee (TNSC): The TNSC shall consist of the each unit's PI, the Coordinating Center PI, (who will coordinate the TNSC activities), and two other independent

researchers. The GPO and at least one other NIMH staff collaborator shall serve as ex officio members of the TNSC. The TNSC shall oversee the scientific aspects of the network activities. Protocols of studies that are funded under this contract shall be approved and progress monitored by the TNSC. The TNSC shall meet as necessary (3-4 times annually). The TNSC shall collaboratively establish rules governing inter-unit sharing of data and data publication, and shall advise the GPO accordingly. The TNSC shall provide recommendations to the GPO in reference to various aspects of contract research activities. Such aspects include, but are not limited, to the:

- Identification, evaluation and prioritization of potential lead compounds to enhance neurocognition in schizophrenia;
- Specific areas of research that are of public relevance and should be the object of the TURNS activity;
- NIMH supported research protocols to be conducted in the TURNS under this contract;
- Methodological aspects of the protocols to be conducted under this contract;
- Alignment of network activities with policy objectives of the NIMH Treatment Development Initiative;
- Means of interface with the National Advisory Mental Health Council (NAMHC) Treatment Development Workgroup with respect to selection of lead compounds for testing within the network.

III. Within nine (9) months of contract award, the Coordinating Center, in collaboration with each TURNS, shall (1) finalize the protocol of the first of the two studies to be conducted in the TURNS and funded during the base period of the contract; (2) develop data collection systems, consent forms, Adverse Event reporting systems, and operations manuals for the first study; (3) obtain an Investigational New Drug (IND) from the Food and Drug Administration (if needed); (4) negotiate with manufacturer and obtain commitment for timely access to study drug and (if applicable) placebo (5) secure IRRB approval at all sites where the first study will be conducted.; (6) develop with the GPO a written site monitoring plan for the TURNS network. At least 2 studies shall be conducted at each TURNS during the base period of the contract. Of these two studies, at least one shall be a clinical efficacy trial and the other a pharmaokinetic and/or dose finding study or pilot efficacy and tolerability study, both of an agent targeting cognitive deficits in schizophrenia as the primary clinical endpoint.

If the TNSC determines that the first study will be a multisite clinical trial, the Coordinating Center P.I., in collaboration with the TURNS P.I.'s will accomplish the tasks outlined in III, (1) – (6) above. If the TNSC determines that the first study will involve individual TURNS sites testing different agents, the P.I. at each individual site will be responsible accomplishing tasks outlined in III (above). In this case the Coordinating Center will be responsible for tracking progress at individual TURNS in accomplishing these tasks and providing the GPO with required documentation.

The protocols of these studies shall: 1) be developed by the TNSC; 2) use the neurocognitive measure developed by the MATRICS contract team; and 3) be consistent with experimental methodology to be outlined in a joint FDA/NIMH conference on treatment development for cognition in schizophrenia scheduled for April 2004. In addition, trials conducted in the network shall comply with the following specifications:

a. At a minimum, each clinical trial shall be an adequately controlled study in patients with schizophrenia who experience significant cognitive deficits unresponsive to conventional pharmacological treatments. Depending on pilot data available for compounds selected for testing, the trial may be a single-site or multisite study with a number of subjects adequate to address the primary hypotheses with a minimum power of 0.80. Sufficient patients should be enrolled in each study to establish proof of concept and/or inform judgment with respect to whether the particular therapeutic agent warrants more extensive evaluation in larger Phase II clinical trials. Although primarily focused on patients with schizophrenia and residual cognitive deficits, for some studies, the sample may include adults suffering from schizotypal personality disorder or individuals with a first degree relative with schizophrenia.

b. At the minimum, any pharmacokinetic and/or pharmacodynamic dose finding study shall be conducted in at least 12 subjects and, in any case, with adequate statistical power to test the study primary hypotheses. Although primarily focused on patients with schizophrenia and residual cognitive deficits, for some studies, the sample may include adults suffering from schizotypal personality disorder or individuals with a first degree relative with schizophrenia.

c. The GPO, in consultation with the TNSC and NAMHC, can identify and propose specific projects related to identifying therapeutic agents targeting cognitive deficits in schizophrenia.

Final selection of protocols and specific medications are subject to modification and recommendations by the GPO according to the needs of the field and feasibility of the proposed projects.

F. Stage Two

1. During months ten(10) through twenty-four (24), the TURNS shall recruit subjects into the first protocol. It is expected that, at a minimum, one fourth of the total number of subjects of the initial protocol shall be enrolled within twelve months of the contract award date, and most, if not all of the remaining patients will be enrolled with twenty months of award.

2. In addition, during months ten (10) through twenty-four (24), the Coordinating Center shall complete the preparation of the second NIMH-supported protocol to be conducted in the TURNS including (1) finalizing the protocol of the second of the two studies to be conducted in the TURNS; (2) develop data collection systems, consent forms, Adverse Event reporting systems, and operations manuals for the second study; (3) obtain an IND from the Food and Drug Administration (if needed); (4) negotiate with manufacturer and obtain commitment for timely access to study drug and (if applicable) placebo (5) secure IRRB approval at all sites where the second study will be conducted.

If the TNSC determines that the second study will be a multisite clinical trial, the Coordinating Center P.I., in collaboration with the TURNS P.I.'s will accomplish the tasks outlined in II (1) – (5), above. If the TNSC determines that the second study will involve individual TURNS sites testing different agents, the P.I. at each individual site will be responsible accomplishing tasks outlined in II (1)- (5) (above). In this case the Coordinating Center will be responsible for tracking progress at individual TURNS in accomplishing these tasks and providing the GPO with required documentation.

G. Stage Three

Full enrollment in the first NIMH-supported protocol should be completed by the end of the 30th month of the contract. Full enrollment and data collection in the second NIMH-supported protocl should be completed by the end of the 45th month of the contract. During months twenty-five (25) through forty-five (45) of the contract, the Contractor(s) shall complete the two research studies described above, perform primary (and if appropriate, secondary) analyses of the research data, and prepare reports for submission to NIMH, FDA (if appropriate), and scientific peer-reviewed journals.

NIMH will provide support under this contract for two clinical trials. By the 35th month of the contract, each TURNS site shall prepare and submit at least one grant application to Federal agencies, private foundations, and/or pharmaceutical companies in order to obtain sufficient funding from sources other than this contract to conduct at least one other study to be initiated before the expiration of this contract. At the minimum, the TURNS shall submit one application for a federal grant, private foundation grant, or pharmaceutical company grant to conduct a pilot evaluation of the efficacy of a pharmacologic agent for the treatment of cognitive deficits in schizophrenia during this period of the contract. TURNS PI's are encouraged to develop collaborative relationships with pharmaceutical and/or biotechnology companies to obtain access to and conduct early phase II trials of novel putative therapeutic agents. The conduct of these studies shall not interfere with the conduct of the studies that are funded under this contract.

H. Meetings/Communications

The Coordinating Center PI shall:

1. Schedule and coordinate periodic telephone conference calls and meetings with the GPO, other NIMH staff, advisors, and other staff involved in the study, in order to discuss the progress of the study and other project-related activities. The frequency of these calls and meetings will depend on the phase of the study, complexity of issues, actual progress, and problems encountered. It is anticipated these calls or meetings shall occur at least monthly throughout the contract, and will likely occur weekly or bi-weekly during the first few months of the contract. The Coordinating Center shall prepare minutes of each call/meeting and send them to the GPO and other relevant parties within a week of the call/meeting;

2. Schedule, coordinate, arrange, participate in, and provide any information necessary for the TNSC meetings. These meetings will be as frequent as required by the phases and progress of the study. It is anticipated that in year 1, at a minimum, a two-day meeting will need to be organized before starting recruitment, in order to finalize the protocol and plan training. The Coordinating Center shall prepare minutes of these meetings and distribute them to the GPO and other relevant parties within 7 working days after each meeting;

3. Schedule, arrange, and coordinate meetings to train TURNS staff in all the relevant activities of the study.

4. Site visit each TURNS at least once a year, to monitor adherence to protocols, to ensure consistency across TURNS sites, and to ensure data is gathered, recorded, and reported in an accurate and timely manner. A schedule for these visits shall be established annually, and provided to the GPO who may choose to attend any or all visits. The Coordinating Center PI should ensure that appropriate personnel conduct each visit, and that the number of attendees

is limited to those necessary in order to optimize contract expenditures. The Coordinating Center shall prepare a written report of each visit, and provide a copy to the GPO and the TURNS site within 15 working days after completion of the visit. Reports shall indicate number of clinical files and procedures audited, number and type of protocol violations or deviations encountered, and number and type of data discrepancies. Reports shall include recommendations and plans to correct any problems encountered at the site.

5. Prepare all required reports for the meetings of the TURNS Data Safety Monitoring Board.

6. Report all Serious Adverse Events to the NIMH GPO within 48 hours on a form to be developed and approved by the GPO for that purpose.

I. Terms and Conditions

1. The Coordinating Center and each TURNS shall, at the time of contract (or subcontract) award, have established all the necessary connections in the local community in order to gain access to an adequate ongoing flow of research subjects during the duration of the contract.

2. All research activities conducted in the TURNS shall follow the state-of-the-art of good clinical research, in order to generate data that can be publishable in peer-reviewed leading scientific journals.

3. All institutional, NIMH, and federal regulations concerning informed consent shall be fulfilled. Protocols and patient consent and assent forms shall be approved by the appropriate institutional review board (IRB).

4. The Coordinating Center shall be responsible for ensuring complete regulatory compliance, as outlined in the FDA regulations, when conducting clinical trials under an Investigational New Drug (IND) applications, if this is required by the type of investigational protocol.

5. Each TURNS shall participate in collaborative activities with the other TURNS. It is expected that these activities shall include, but not be limited to, exchanging scientific and technical expertise, planning, organizing, and conducting specific research studies, and analyzing, interpreting and publishing scientific reports based on the research data.

6. Data collected by the TURNS from the specific studies funded by NIMH under this contract (i.e., selected and monitored directly by the GPO in coordination with the TNSC) shall be property of the NIMH and shall be made available to NIMH both electronically and in hard copy using standard procedures that guarantee the confidentiality of the research records. All publications of study-related results shall be coordinated with the Publications Committee and the GPO.

7. No data from studies funded by NIMH under this contract shall be released, presented at meetings or published, unless the data have been accepted by the Publications Committee and coordinated with the GPO. It is expected that the GPO and other Government officials involved in the activities conducted under this contract shall publish study data jointly with the Coordinating Center and other TURNS staff.

8. NIMH shall have the right to audit patient records and research data at any time during the contract.

9. The Coordinating Center shall be responsible for all aspects of the performance of this contract, including the performance of any subcontractor. Note that all subcontracts must be approved by the contracting officer prior to their award.

10. Work under this contract shall be monitored by the GPO.

11. The Chief Neuropsychologist, the Clinical Pharmacologist, and the PI (if not one of these individuals) shall be key personnel and shall not be replaced without the approval of the GPO as specified in the Key Personnel Clause.

12. Note: The sites will have a forty-five (45) month period in which to conduct the tasks. The Coordinating Center shall have forty-eight (48) months (an additional three (3) months) in order to complete wrap up tasks on the project

J. Reporting Requirements/Deliverables

1. Within one (1) month of contract award, the Coordinating Center shall finalize the draft work plan included in the proposal, and submit three (3) copies to the GPO. The work plan shall include, but not be limited to, the timetable and methodology/plan for implementing the first protocol to be conducted in the TURNS.

2. At least every 2 months, the Coordinating Center shall submit to the GPO a brief report on the TURNS activities. This report shall not include patient identifiable information. The report should include, at a minimum:

   - List of active research projects of the TURNS (both funded under the contract or through other mechanisms);

   - Status of each project funded under this contract, including information on recruitment, the number of research subjects enrolled, the number of patients who dropped out or were temporarily withdrawn from the study, or completed the protocol;

   - Status of studies being planned or developed.

   - Any significant and/or unexpected adverse events and difficulties in the organization or conduct of the study;

   - Status of data management and analysis;

   - Summary of meetings, including any determination/recommendations made by the TNSC and DSMB.

   - Any other information pertinent to the contract.

3. Within six (6) months from the date data is locked on each protocol funded under this contract, the Coordinating Center shall submit a final report to the GPO for that protocol.

At that time, the Coordinating Center shall also submit a copy of the research data (both in electronic from and in hard copy) for that protocol to the GPO.

4. If requested by the GPO, biological specimens collected as part of research protocols funded by NIMH under this contract will be made available to the Government and/or transferred to a repository designated by the GPO.

5. The Coordinating Center shall submit a final report on or before the contract completion date.

K. Other Aspects and Unit Objectives

1. It is expected that most of the studies conducted in the TURNS shall be clinical and conducted in adult patients with schizophrenia. However, clinical studies in non-schizophrenia adults may be conducted if they are considered important prerequisite for proper investigations with schizophrenia populations.

2. Any investigator of a host institution affiliated with a TURNS who has the necessary expertise in schizophrenia, neurocognition, and neuropharmacology is eligible to utilize the TURNS resources for studies of drug safety, efficacy, and metabolism, if their protocols have been approved and prioritized by the LAC. Such studies must not delay or negatively interfere with the conduct of the studies funded by NIMH under this contract.

L. Non-Reimbursable Contract Costs

Costs of clinical care, such as patient bed costs, outpatient visit fees and clinical laboratory determinations shall not be reimbursable under this contract. This shall include tests and procedures that are clinically required for standard treatment of the patient and are routinely performed for a fee in institutional laboratories.

Addendum A

Selection of the TURNS Sites

Each site will provide a proposal, an agreement to comply with the protocols to be agreed upon by the TNSC, fixed cost per patient, and will meet the criteria listed below:

1. Access to a sufficient number of potential study participants to ensure prompt enrollment of study subjects and timely completion of the study.
2. Diversity of subjects including a range of ages, sexes, ethnic diversity, and geographical dispersion (including a balance between urban and rural).
3. Availability of adequate experienced professional and technical staff to provide scientific and administrative coordination and support to the clinical trial, including site management and quality control expertise, appropriate clinical expertise, and capacity for patient recruitment and followup.
4. Adequate facilities, equipment, and support staff to conduct clinical trials.
5. Adequate computing resources and support staff, including internet access, and electronic communication capabilities.
6. Any needed capabilities and staff for data collection, entry, editing, electronic transfer, quality control, database management (maintaining security and accessibility), and data backup (on site and off site).
7. Agreement to participate as a site for this trial.
8. Agreement to comply with all the required Federal Acquisition Regulation (FAR) and Health and Human Services Acquisition regulation (HHSAR) clauses.
9. Sample Terms & Conditions for TURNS Subcontracts:
    a. At the time of award, the clinical site shall have an established source of research subjects appropriate for the protocol design.
    b. All research activities conducted at the study site shall follow the state-of-the-art of good clinical trial practice criteria, in order to generate data that can be published in peer-reviewed scientific journals.
    c. All institutional, NIMH, and federal regulations concerning informed consent shall be fulfilled. Protocols and patient consent forms shall be approved by the appropriate IRB.
    d. All materials/data collected from the specific study funded under this contract shall be property of the NIMH and shall be made available to the NIMH both electronically and in hard copy using standard procedures that safeguard the confidentiality of the research records. It is anticipated that the GPO and other Government officials involved in the activities conducted under this contract will publish study data jointly with the PIs and TURNS staff. Publication will be in accordance with the Terms and Conditions of the Contract Statement of Work.
    e. NIMH or its designees shall have the right to audit patient records and research data at any time during the study.

f. The clinical site leader shall be responsible for all aspects of the performance of this contract, including the performance of any subcontracts. All subcontracts require prior review and approval of the GPO and Contracting Officer (CO) before award.
g. Work under this contract shall be monitored by the GPO, PI, and TNSC.

Addendum B

Protocol Development:

The Contractor shall complete the development of a protocol using whatever mechanisms deemed to be appropriate.
At a minimum, the final protocol shall include the following aspects:

1. A review of the study objectives, public health significance, specific aims, and endpoints.
2. A review of the compound to be tested including preclinical studies, human safety data, pilot human efficacy data, mechanism of action, pharacokinetics, dosage considerations, and rationale for dosage and duration of treatment.
3. Trial design and administrative structure.
4. Treatment specifications (with attachment of treatment manuals, as needed) and length of treatment.
5. Patient selection criteria with rationale for limited exclusions.
6. Enrollment of women and minorities.
7. Randomization and stratification/blocking methods.
8. Primary and secondary efficacy measures.
9. Outcome measures (where appropriate) to examine issues such as compliance, disability, vocational function, social function, and quality of life.
10. Outcome measures (where appropriate) to evaluate how external factors (setting, psychosocial support, economic factors, etc) impact treatment delivery, and outcome.
11. Sample size and power estimates.
12. Clinical and laboratory monitoring procedures.
13. Reporting of adverse events.
14. Plans for subject retention and minimization of dropouts.
15. Plan for dealing with slow enrollment.
16. Rules for dealing with exacerbations, hospitalizations, and treatment failures.
17. Plans for dealing with clinical emergencies and breaking of masked treatment (if applicable).
18. Stopping rules and possible rerandomization rules.
19. Acquisition of drugs.
20. Rules for possible dosage adjustments.
21. Plan for dealing with existing medications as patients enter trial.
22. Rules for adjunctive pharmacologic, psychotherapeutic, or other treatment.
23. Plans for preventing, identifying, and handling protocol violations.
24. Procedures for addition and/or removal of clinical sites.
25. Rules for interim analysis and early termination of a treatment arm if appropriate.
26. Plans for study staff training; cross-site maintainance of reliability and prevention of rater drift.
27. Plans for monitoring and coordination of each site.
28. Data collection and monitoring.
29. Human subjects considerations and sample consent forms.
30. Data analysis plans.
31. Plans for disseminating findings from the trial.
32. A timeline with milestones and evaluation criteria against which progress of the trial will be judged.
33. Plans (if applicable) for insuring post-study access to study drug for patients who respond.

Protocol Implementation

The Coordinating Center shall perform all the activities necessary for a proper conduct of the study, including, among others:

1. Monitor Sites for rate of recruitment, protocol adherence, data collection, data entry and ensure quality performance at each site.
2. Ensure that adequate supply of study medication is available at each site.
3. Ensure adequate monitoring and prompt reporting of adverse medical events.
4. Ensure data transfer from the sites to the coordinating center.
5. Assess the quality of the data received from the sites and verify (if needed) the database against any source documentation.
6. Prepare and send monthly reports to the GPO that include, at a minimum, the following information, both by individual Site and cumulative: number of subjects enrolled and their demographic characteristics, number of subjects screened but not enrolled with reason for non enrollment, number of subjects who dropped out of the protocol and reasons, number of subjects who have completed the study, anticipated subject enrollment and completion schedules.
7. Prepare and distribute reports for the DSMB (on average every 3 months during the conduct of the study), the GPO, and TNSC, as requested.

Addendum C

Clinical Trial Preparation

The following tasks shall also be completed within nine (9) months from the award of the contract to ensure that patient enrollment begins on schedule:

1. Develop the text of the first study consent and assent forms for use by the clinical sites, provide the sites with such documents, and ensure that, after appropriate modifications to meet local standards, these forms are approved by the IRB at each Site;
2. Submit to the GPO all materials necessary to obtain approval of a clinical exemption from the NIH Clinical Exemption Review Committee before the start of patient enrollment into the protocol and all materials necessary to obtain approval of the Office of Management and Budget (OMB) if required;
3. Develop and test procedures for collecting all data needed on study subjects, using either standardized clinical research forms or an electronic equivalent;
4. Prepare manuals of study policies and procedures;
5. Pilot test all forms and procedures before their finalization and distribution to the Sites;
6. Arrange and coordinate training of the clinical staff, in order to ensure reliability of evaluation, treatment and assessment procedures;
7. Develop and implement a system for random treatment assignment of eligible patients and appropriate stratification;
8. Obtain study medications and prepare them for proper use in the study;
9. Develop and implement a plan for closely monitoring adverse effects of study medications to maximize patient safety, including plans for prompt reporting of the more severe adverse events;
10. Develop and implement a plan for subject retention and a system for dealing with clinical emergencies, both acute and subacute (hospitalization, adjunctive medications, etc.);
11. Develop a plan for overall quality control and for monitoring patient recruitment and for early identification of Sites with recruitment problems and for addressing recruitment difficulties;
12. Develop a plan for dropping a Site should the Site not be able to maintain minimal recruitment goals and for adding new Sites as necessary or appropriate.

Addendum D

Computer System

The contractor shall develop a data collection and management system suitable for the study. This should be a commercially available, relational database management system (DBMS) that is fully ANSI SQL compliant, and that runs on a UNIX or Microsoft platforms NT Windows 2000. Data entry/verification procedures should minimize opportunities for human error and other incorrectly entered data. If feasible, and if it does not delay study onset, NIMH encourages the use of electronic forms for initial entry of individual subject data by on site staff (with a paper printout). In this case, the contractor may choose to provide a standardized data management system to each Clinical Site, or work with existing compatible systems at each Site. Alternatively, if initial entry of subject data is done using paper based forms, data entry may be done at the TURNS site or the Coordinating Center. At a minimum, the system shall provide for the following:

1. Internet access and capacity for electronic communications. NIMH anticipates that the contractor will develop a secure Intranet to facilitate interactions between TURNS, the Coordinating Center, and NIMH. A method must be provided to ensure security and confidentiality of all clinical records (including, if applicable, HIPAA requirments).

2. On-site and off-site backup of electronic data is necessary, as well as procedures to avoid data loss and down-time in case of equipment failure (e.g., hard disk crashes computer breakdowns, power outages, etc.).

3. While NIMH does not plan to do so, at the request of the GPO and CO, the contractor shall close out data entry and transfer the entire database, Relational Database Management System (RDBMS), and all associated programs, source code, codebooks, indices, data tables, documentation, etc., within 30 calendar days of such notification, in a readily usable form to NIMH and/or to its designee. The computer system, RDBMS, and any software used to enter, store, manipulate and report study data must be transferable and reproducible. Site specific and legacy systems are to be avoided, and any programs written by RDBMS staff must be executable on systems available to NIMH and/or third parties.

Data Management Activities

The Coordinating Center shall have all the necessary procedures operational to perform the following activities to be conducted at different times during the duration of the contract:

1. A standardized method of data entry and data verification.
2. A method and schedule for transferring data (electronic and/or paper) from the TURNS to the Coordinating Center.
3. The DSMB must be able to receive, process, edit, correct, update, store, track, retrieve, and analyze all study data.
4. Data entry, verification, and transfer procedures, and the RDBMS as a whole, shall be tested prior to patient recruitment to ensure reliable performance.
5. The Coordinating Center shall monitor TURNS data collection, subject tracking, and transfer of data to the Coordinating Center. The Coordinating Center shall train staff at the TURNS

in proper procedures and standards to ensure prompt accumulation, completeness, entry, and editing of study data. Procedures for entering and verifying data shall be established and in place.

6. The Coordinating Center shall establish standards to measure and monitor how accurate, complete and up to date the database is. There will be a plan for resolving problems identified in the monitoring process.
7. As data are received from the TURNS, the Coordinating Center shall, as needed, check, enter (if received as hard copy), verify, process, monitor, correct, update, file, store, and inventory the data using the DBMS. Data received from the TURNS shall be reviewed within one week from receipt for completeness, accuracy, consistency, out-of-range values, and overall quality. Sites shall be informed promptly, and in any case within 2 weeks from receipt of any missing, incomplete, or erroneous data.
8. The Coordinating Center shall develop appropriate methods for analyzing and presenting study data using standard statistical software capable of univariate and multivariate analyses;
9. The Coordinating Center shall develop procedures to be used by the PIs and the GPO to obtain (through RDBMS staff) data from the database in either raw or summary form, for reports and analysis. The information will be provided electronically and/or as hard copy depending on the request. The PIs and GPO shall specify standard (recurrent) database queries that should be immediately answerable (less than 24 hours) by the data managers. Other, non-standard database queries shall be answered within 7 calendar days.
10. The Coordinating Center shall prepare and provide periodic study data and reports as requested by the GPO, the PIs, and the NIMH DSMB.
11. On or before the final date of the contract, the Coordinating Center shall provide the GPO with the RDBMS, a final, cleaned, edited, and documented database containing all study data, and all associated programs, source code, codebooks, indices, data tables, documentation, etc, in a format that is readily usable by NIMH or its designee.
12. On or before the final date of the contract, the Coordinating Center shall provide the GPO with final statistical reports of the study outcomes.
13. The data management system should allow the NIMH GPO to access data regarding serious adverse events (SAE), including SAE summaries, study ratings and clinical source documents within 24 hours of the SAE.

ATTACHMENT 2

REPORTING REQUIREMENTS AND DELIVERABLES
RFP NO. NIMH-03-DM-0003

1. Period of Performance
Performance of this contract shall begin on the effective date of the contract (EDOC) and shall not exceed beyond the estimated completion date of the contract unless the period is extended by modification to the contract. The period of performance of this contract is four (4) years commencing from the effective date of this contract.

Note: The sites will have a forty-five (45) month period in which to conduct the tasks. The Coordinating Center shall have forty-eight (48) months (an additional three (3) months) in order to complete wrap up tasks on the project

2. Delivery and Reports Schedule
After the contract award date, the Contractor shall deliver the following items to the Government Project Officer (GPO) and Contract Officer (CO) in accordance with the delivery schedule set forth below:

DELIVERABLE	DUE	# Copies	Due to
Workplan (see K.1.)	Due 1 month after EDOC	4	3 copies to GPO, 1 copy to CO
Monthly Progress Report (detailing expenditures and activities carried out during the month. The progress report is intended to provide document support for the justification of costs and payment of the monthly voucher.)	Monthly, to accompany voucher/invoice	2	1-GPO, 1-CO
Bi-monthly Reports (See description of what to include in report under J.2.)	Due every 2 months	4	3-GPO 1-CO
Protocol and Research Data (See J.3)	Due 6 months from EDOC	3	3-GPO
Annual	12 months after EDOC 24 months after EDOC 36 months after EDOC	3	2-GPO 1-CO
Final	48 months after EDOC	3	2-GPO 1-CO
Other materials or Ad hoc reports	As requested		

3. Clauses Incorporated by Reference (FAR 52.252-2 - JUN 1988)

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. A full text of this clause may be accessed electronically at the following address: http://www.arnet.gov.

FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER I) CLAUSES

52.242-15 Stop Work Order (AUG 1989) Alternate I (APR 1984)
52.246-8 Inspection of Research and Development – Cost Reimbursment (April 1984)

ATTACHMENT 3
EVALUATION CRITERIA FOR AWARD

I. GENERAL-BASIS FOR AWARD

The evaluation will be based on the demonstrated capabilities of the offerors in relation to the needs of the project as set forth in the RFP. The merit of each proposal will be evaluated carefully, based on responsiveness to the RFP and thoroughness and feasibility of the technical approach taken. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below under item III.

The acceptability of the technical portion of each contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

Failure to provide the information required to evaluate the proposal may result in rejection of that proposal without further consideration. Proposals which merely offer to conduct a project in accordance with the requirements of the Government's scope of work will be considered non-responsive to this request and will not be considered further. Offerors must submit an explanation of the technical approach and a detailed description of the tasks to be performed to achieve the project objectives.

II. RELATIVE IMPORTANCE OF TECHNICAL AND COST FACTORS

Selection of an offeror for contract award will be based on an evaluation of proposals against four (4) factors. The factors, in order of importance are Technical, Past Peformance, Small disadvantaged business participation (SDBP), and Cost/Price. Although technical factors are of paramount consideration in the award of the contract, past performance, SDBP and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award to that offeror whose proposal provides the best overall value to the Government.

Offers from qualified HUBZone firms and small disadvantaged business concerns may have special evaluation terms as explained in this attachment below.

The small disadvantaged business participation (SDBP) factor is explained in this attachment below.

Proposals are intended to be evaluated and award made after discussions with offerors, but an award may be made without discussions with offerors.

III. TECHNICAL EVALUATION CRITERIA AND ASSIGNED WEIGHTS

The technical evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. Proposals will be judged solely on the written material provided by the Offeror. Proposals submitted in response to this RFP will be evaluated based on the following factors, which are listed and weighted to indicate their relative importance.

CRITERIA	**WEIGHT**
A. UNDERSTANDING OF THE PROBLEM	10

The proposal shall provide a statement, in the Offeror's own words, of the goals, objectives, scope and purpose of the project to demonstrate a complete understanding of the intent and requirements of the contract. This discussion should include a discussion of potential difficulties which may arise in the performance of the work, and, quality control measures.

B. TECHNICAL APPROACH 50

The evaluation will assess the soundness and practicality of the technical approach for responding to the objectives as stated in the Statement of Work, with adequate justification and substantiation for the recommended methods. The proposed technical approach shall comply with each of the requirements specified under the Description and Scope of work and the Delivery Schedule, including phasing of tasks and methods to be utilized. The detailed work plan is to be included with the Technical Proposal and shall include the following:

1. A discussion of the technical approach for Stages 1, 2 and 3 as well as a discussion of how the TURNS will work as a network of research units/sites, identifying promising potential procognitive therapeutic agents, and conducting high priority clinical studies focused on enhancing neurocognition in schizophrenia including (but not limited to) general safety profile, drug-drug interactions, efficacy (particularly early proof of concept), dose ranges, dose regimen, pharmacokinetics, and effect on other dimensions of symptomatic and behavioral disturbance in schizophrenia. In addition, the work plan shall discuss how the TURNS will promote the validation of specific measures of cognition in schizophrenia for use as endpoints in clinical trials and refine methodological approaches for determining the efficacy of compounds for this indication. In addition to the above considerations, the work plan shall also:

a) develop and fully elaborate the key elements of the study design, including research objectives outlining the proposed experimental methodology for accomplishing the objectives, a plan for ensuring consistent and replicable administration of the protocol within and across sites, and, a plan for collection of data and quality control of data collection;

b) develop and fully discuss the technical approach for clinical trial preparation and conduct, including discussion of the two (2) studies to be conducted at each TURNS during the base period of the contract, with at least one being a clinical efficacy trial and the other a pharmaokinetic and/or dose finding study or pilot efficacy and tolerability study, both of an agent targeting cognitive deficits in schizophrenia as the primary clinical endpoint, and, discussion of the studies to be performed during the option period;

c). discuss the approach for proactively seeking grants from public or private entities for conducting a pilot evaluation of the efficacy of a pharmacologic agent for the treatment of cognitive deficits in schizophrenia, and, **developing collaborative relationships with companies to obtain access to and conduct early Phase II trials of novel putative theraputic agents**.

2. The work plan shall describe the Coordinating Center's technical approach for recruting clinical sites with the appropriate infrastructure, facilities and experience in conducting related clinical trials, and shall at a minimum describe:

a) how the Coordinating Center shall work collaboratively with each TURNS, to: (1) develop, implement and finalize the protocol of the studies to be conducted in the TURNS and funded during the base and option period of the contract; (2) develop data collection systems, consent forms, Adverse Event reporting systems, and operations manuals for the first study; (3) obtain an Investigational New Drug (IND) from the Food and Drug Administration (if needed); (4) negotiate with manufacturer and obtain commitment for timely access to study drug and (if applicable) placebo (5) secure IRB approval at all sites where the first study will be conducted.; (6) develop with the GPO a written site monitoring plan for the TURNS network;

b) how logistical aspects, training, interactions, adequate recruitment of subjects, and other activities shall be coordinated for the TURNS network; and

c) automation of TURNS network activities, including website development, systems capability, technical environment and architecture to protect and share data, data collection and analysis, security measures and quality control procedures.

C. PERSONNEL & MANAGEMENT PLAN 40

The proposal shall evidence:

1. the availability of staff at the Coordinating Center and TURNS units with the appropriate training, expertise and experience, required to plan and implement TURNS activities, including:

   a. Roles, responsibilities, and lines of authority of staff in these activities. (*See Sample Staff Loading Chart and Other Documentation below)
   b. Documentation to reflect and explain previous efforts that reflect length and variety or experience in the area of cognition in schizophrenia and clearly demonstrate specific accomplishments.
   c. Expertise of professional personnel in the areas of cognitive processes.
   d. Experience of professional personnel in managing large, multi-center clinical trials providing data in support of FDA-accepted New Drug Applications.

2. experience of Principal Investigator (PI) in managing teams of scientific investigators, and in overall administrative ability to direct the project, including; (a) demonstrated knowledge of issues of schizophrenia as manifested by the PI's active participation in the scientific community and journals; (b) organizational ability and support to coordinate trials and ability to identify, select and motivate sites as well as demonstrated ability to conduct clinical trials within budget and timelines; (c) relationship with academia and industry investigators that facilitate obtaining compounds related to cognition in schizophrenia; (d) demonstrated track record of contribution to the literature of neurophyschology of cognition in schizophrenia and/or prior participation in clinical trials targeting cognition in schizophrenia; (e) evidence of prior funded support for cognition in schizophrenia from diverse funding organizations such as Federal, Foundations and Industry.

TOTAL POINTS----------100

* SAMPLE STAFF LOADING CHART AND OTHER DOCUMENTATION (referenced in C.1. above)

1)The offeror should provide a detailed staff loading chart for each component, identifying all staff who will participate in the coordinating center(s) (including individuals not paid from this Contract). This should be provided in a tabular format, and must include the name of the individual, the task to be performed, the percent of the individual's total effort to be spent on that task for the Contract, how much of that percent effort will be paid for by the Contract (i.e., if an individual will spend 20% of total effort on a task, and the Contract will pay for half of this, the Contract Support Percentage would be 10%), and estimated total hours per year for that individual and that task. For example (assuming a 40 hr work week and 50 weeks worked per year):

Name	Task	% Effort	Contract %	Total hrs/yr
Mary Roe	Monitor sites	50%	50%	1000
John Doe	Secretary	20%	10%	200

2)For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.
-Their availability to the project and the amount of time anticipated.
-Willingness to act as a consultant.
-How rights to publications and patents will be handled.

3)Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

IV. PAST PERFORMANCE (See attachment 7)

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offerors, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offerors' likelihood of success in performing the acquisition requirement as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's businelike-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

V. HUBZONE SMALL BUSINESS CONCERNS

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, incorporated by reference into this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

VI. OFFERS FROM SMALL DISADVANTAGED BUSINESS FIRMS:

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Attachment 5, RFP References, offerors will be evaluated by adding a factor of 10 percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23, which can be found on-line at http://www.arnet.gov/far/

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment. AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

VII. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

This factor entitled “Extent of Small Disadvantaged Business Participation” shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). TheNAICS codes can be found at:

http://www.sba.gov/size

The Department of Commerce website for the annual determination is:

http://www.arnet.gov/References/sdbadjustments.htm .

Offerors shall include with their offers, SDB targets, expressed as percentages of total contract value, in each of the applicable, authorized NAICS Subsector(s). The applicable authorized NAICS Subsector(s)

for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Technical Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the "Small Business Subcontracting Plan," if it is required by this solicitation.

SDB participation will not be numerically scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's plan provided with the business proposal (see format for plan provided below. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

NOTE: The "SDB Participation Plan" is not to be confused with the "Small Business Subcontracting Plan" referenced in attachment 4, under "Just in Time."

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified
(b) Extent of commitment to use SDB concerns
(c) Complexity and variety of the work SDB concerns are to perform
(d) Realism of the proposal
(e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation.
(f) Extend of participation of SDB concerns in terms of the value of the total acquisition

Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

OFFERORS - PLEASE COMPLETE THE PLAN BELOW AND INCLUDE IT IN THE TECHNICAL PROPOSAL

Small Disadvantaged Business Participation Plan

1. The extent of an Offeror's commitment to use SDB concerns.
Directions: Commitment should be as specific as possible, i.e., SDB concerns are specifically identified, subcontract arrangements are already in place, letters of commitment are attached to the SDB plan, etc. Specific SDB concerns must be identified with points of contact and phone numbers. Enforceable commitments will be weighted more heavily that non-enforceable ones. Targets expressed as percentage of total contract value for each SDB participating will be incorporated into and become part of any resulting contract. The extent of participation of all SDB concerns in terms of the value of the total acquisition must be identified. NOTE: Additional weight will not be given simply for higher percentages of work going to SDBs if that work is deemed unnecessary to the requirements of the SOW or, unnecessarily elaborate or frivolous and, included merely to boost the appearance of SBD participation.

RESPOND HERE:

_____
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_____
_____
_____

2. The complexity and variety of the work SDB concerns are to perform.
Directions: Greater weight will be given for arrangements where the SDB shall be performing a greater variety of work, and work of greater complexity.

RESPOND HERE:

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_____
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_____

3. Fairness, reasonableness, and realism of costs proposed by SDBs for the work they will perform.
Directions: Provide information regarding how the Offeror determined that the SDB costs are fair and reasonable. NOTE: DO NOT provide actual costs, but rather the process that you followed to ensure reasonable costs, i.e. competition, negotiation, discussions, etc.

RESPOND HERE:

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_____
_____

4. Past performance of the Offeror in complying with subcontracting plans for SDB concerns. *Directions: An Offeror with an exceptional record of participation with SDB concerns will receive a more favorable evaluation than another whose record is acceptable. Please explain your track record in compliance with subcontracting plans for SDB concerns.*

RESPOND HERE:

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_____

VIII. HUMAN SUBJECTS EVALUATION

1. This research project involves human subjects. NIH policy requires:

   a. Protection of Human Subjects from Research Risks

      The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NIMH that a designated exemption is appropriate.

      If concerns are identified you will be afforded the opportunity to further discuss and/or clarify your position during discussions and in your Final Proposal Revision (FPR). If, after discussions, concerns still exist, your proposal may not be considered further for award.

   b. Data and Safety Monitoring (see page 56 for detailed information regarding Data and Safety Monitoring)

2. Women and Minorities

   Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for Phase III clinical trials, it is required that all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable, unless the Government has specified in the Statement of Work that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups.

   Where the offeror determines that inclusion of women and minority populations is not feasible, a detailed rationale and justification for exclusion of one or both groups from the study population must be submitted with the technical proposal. The NIMH will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research.

If the rationale is not considered acceptable by the Government and you are included in the competitive range, you will be afforded the opportunity to further discuss, clarify, or modify your plan for inclusion in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

3. Children

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are scientific and ethical reasons not to include them.

The offeror's proposal must include a description of plans for including children. If children will be excluded from the research, the proposal must present an acceptable justification for the exclusion. If the offeror determines that exclusion of a specific age range of child is appropriate, the proposal must also address the rationale for such exclusion.

If the information about the inclusion of children is absent or considered inadequate, you will be afforded the opportunity to further discuss, clarify or modify your plan for inclusion in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

Attachment 4
INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

A. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (reference attachment 5), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541720.

(2) The small business size standard is 6 million.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in EVERY solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

B. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that one award will be made from this solicitation and that the award will be made on/about September 30, 2002.

It is anticipated that the award from this solicitation will be a multiple-year, cost reimbursement type contract with a period of performance of four (4) years and that incremental funding will be used [see Attachment 4, Business Proposal Instructions].

C. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

D. SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from: Contracting Officer

Contract Management Branch
NIMH, NIH
6001 EXECUTIVE BLVD, Room 8153
BETHESDA MD 20892-9603

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

E. HHSAR 352.223-70 SAFETY AND HEALTH (JANUARY 2001)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State and local laws and regulations applicable to the work being performed under this contract. These laws are implemented and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration and other agencies at the Federal, State and local levels (Federal, State and local regulatory/enforcement agencies).

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer in conjunction with the project or other appropriate officer, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, an equitable adjustment will be made in accordance with the applicable "Changes" Clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; and/or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply promptly with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor. (End of clause)

F. INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

In addition, the Offeror should mark each page of data it wishes to restrict from public disclosure with the following statement, “Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal.”

(1) **General Clauses**

Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addresses, and marked as indicated in the cover letter to this Request for Proposal package. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in Attachment 4 and 5.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in Attachment 4 and 5.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Attachment 5, PROPOSAL SUMMARY AND DATA RECORD.)

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment 5, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF

LABOR AND DIRECT COSTS). However, the technical proposal should **NOT** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

For example: In the event offerors propose in teams and the Government deems it favorable that individual contracts are awarded to each TURNS site, one site must be identified as the Coordinating Center, with the role of the Coordinating Center clearly defined in the proposal, and each proposed TURNS site shall indicate their willingness to cooperate with the monitoring activities of the Coordinating Center. The proposals shall be clearly marked "Alternate Proposal" and the offeror(s) must still also submit a proposal for the performance of work as specified in the SOW.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in Attachment 3 this RFP.

(7) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurement, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

> **Hard Metric** - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) **Privacy Act - Treatment of Proposal Information**

The Privacy Act of 1974 (P.L. 93-579) [see information at the following website: http://oma.od.nih.gov/ms/privacy/], requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

-to the cognizant audit agency and the General Accounting Office for auditing.

-to the Department of Justice as required for litigation.

-to respond to congressional inquiries.

-to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(10) The Health Insurance Portability and Accountability Act (HIPAA) of 1996 may apply to this project. More information about HIPAA standards can be found at: www.cms.gov/hipaa

(11) Discussions with offerors will be conducted in accordance with FAR 15.101-1, 15.306 and HHSAR 315.370.

(12) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

(13) **Institutional Management of Conflicting Interests**

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(14) **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

(15) **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

(1) Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
(2) Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
(3) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
(4) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
(5) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).
(6) Instructions To Offerors--Competitive Acquisition [Far Clause 52.215-1 (May 2001)] Alternate I (October 1997).

G. TECHNICAL PROPOSAL INSTRUCTIONS

1. Although there is no specific number of TURNS sites required by this solicitation, it is recommended that each offeror will be comprised of no less than 4, and no more than 6 sites headed by investigators with the appropriate expertise and access to patient populations in different geographic areas, with a target of 60 subjects per site.

It is anticipated that a single contract will be issued for the project as a whole, and the primary contractor shall operate as the Coordinating Center and issue subcontracts to each TURNS. The terms and conditions of the primary contract shall apply to the TURNS subcontracts. It is further anticipated that the TURNS subcontracts will be paid based on benchmarks at fixed amounts rather than on a per patient basis. The Coordinating Center/Contractor shall fully describe in their proposal the proposed payment plan for the TURNS subcontracts.

For proposing teaming arrangements, see Attachment 4, Item F, (5) Alternate Proposals.

2. Work Plan

A detailed work plan (see Attachment 3) must be submitted with the technical proposal. OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT. (Reference Attachment 5 - Form of other support)

3 Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

4. Past Performance Information

a) Offerors shall mail the Past Performance Questionnaire and Letter to at least five previous clients (see Attachment 7) that are representative of the Offeror's capability to perform the services described in this solicitation.

b)IN ADDITION, Offerors shall submit the following information in their proposal (for both the Offeror and proposed major subContractors):

a) A list of the contracts completed during the past three years and all contracts currently in process that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

b) IMPORTANT – Please ensure that all contact information that is submitted is up to date, i.e. please contact the organizations before including them in your proposal to ensure people, addresses and numbers have not changed.

Include the following information for each contract or subcontract:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's name and telephone, e- mail and fax number (ensure current information)
7. Program Manager's name and telephone, e- mail and fax number (ensure current information)
8. Standard Industrial Code

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

5. **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

6. **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

7. **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

8. **Information Technology Systems Security**

If this project involves Information Technology, the proposal must present a detailed outline of its proposed Information Technology systems security program which complies with the requirements of the Statement of Work, the Computer Security Act of 1987 Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May, 1994). The proposal will also need to include similar information for any subcontract proposed.

NOTE: OMB A-130 is accessible via web site:
http://www.whitehouse.gov/WH/EOP/OMB/html/circular.html

9. **GOVERNMENT NOTICE FOR HANDLING PROPOSALS**

NOTE: This Notice is for the Technical Evaluation Review Group who will be reviewing the proposals submitted in response to this RFP. THE OFFEROR SHALL PLACE A COPY OF THIS NOTICE BEHIND THE TITLE PAGE OF EACH COPY OF THE TECHNICAL PROPOSAL.

GOVERNMENT NOTICE OF HANDLING PROPOSALS

This proposal shall be used and disclosed for evaluation purposes only, and a copy of this Government notice shall be applied to any reproduction or abstract thereof. Any authorized restrictive notices which the submitter places on this proposal shall be strictly complied with. Disclosure of this proposal outside the Government for evaluation purposes shall be made only to the extent authorized by, and in accordance with, the procedures in HHSAR paragraph 352.215-1.

(a) If authorized in agency implementing regulations, agencies may release proposals outside the Government for evaluation, consistent with the following:

(1) Decisions to release proposals outside the Government for evaluation purposes shall be made by the agency head or designee;

(2) Written agreement must be obtained from the evaluator that the information (data) contained in the proposal will be used only for evaluation purposes and will not be further disclosed;

(3) Any authorized restrictive legends placed on the proposal by the prospective Contractor or subcontractor or by the Government shall be applied to any reproduction or abstracted information made by the evaluator;

(4) Upon completing the evaluation, all copies of the proposal, as well as any abstracts thereof, shall be returned to the Government office which initially furnished them for evaluation; and

(5) All determinations to release the proposal outside the Government take into consideration requirements for avoiding organizational conflicts of interest and the competitive relationship, if any, between the prospective Contractor or subcontractor and the prospective outside evaluator.

(b) The submitter of any proposal shall be provided notice adequate to afford an opportunity to take appropriate action before release of any information (data) contained therein pursuant to a request under the Freedom of Information Act (5 U.S.C. 552); and, time permitting, the submitter should be consulted to obtain assistance in determining the eligibility of the information (data) in question as an exemption under the Act. (See also Subpart 24.2, Freedom of Information Act.)

10. **Human Subjects**

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (SEPTEMBER 1985)

a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office of Protection from Research Risks (OPRR), National Institutes of Health (NIH), Bethesda, Maryland 20892*****. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.

c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The National Institutes of Health will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OPRR*****, (telephone: 301-496-7014*****), is recommended.

e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR***** an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning

responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR* and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

f) It is recommended that OPRR* be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. (End of Provision)

**Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this provision. The phone number to reach this office is 301-496-7014. For more information, the OHRP website may be accessed at http://ohrp.osophs.dhhs.gov/*

11. **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. This site may be downloaded at no cost and modified for use by the offeror, if desired. In addition, the University of Rochester has made available its training program for individual investigators, and completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/order/pubs_profs_protect.html. If an institution has

already developed educational programs on the protection of research participants, completion of these programs will also satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the contracting officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

12. **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of an Institute/Center Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of clinical research adopted in June2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research" (http://www.nih.gov/news/crp/97report/execsum.htm).

The revisions relating to NIH defined Phase III clinical trials and require: a) all proposals and/or protocols to provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference), by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences. The proposal must also include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect amoun sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include an analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

In addition, the proposal should contain a description of the proposed outreach programs for recruiting women and minorities as participants

The form entitled, "Targeted/Planned Enrollment Table," should be used when preparing your response to the solicitation requirements for inclusion of women and minorities. (Reference Attachment 5).

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Unless otherwise specified in this solicitation, the Government has determined that the work set forth herein does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See attachment 3 of this RFP for more information about evaluation factors for award.)

The format for the Annual Technical Progress Report for Clinical Research Study Populations (See Section J - List of Documents, Exhibits and Other Attachments of the RFP) entitled, "Inclusion Enrollment Report," shall be in reporting in the resultant contract. (Reference Attachment 5).

13. **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are scientific or ethical reasons not to include them. For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. In the technical proposal, the offeror should create a section titled "Participation of Children." This section should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. The RFP will contain a review criterion addressing the adequacy of plans for including children as appropriate for the scientific goals of the research, or justification of exclusion.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.html

Offerors may also obtain copies from the contact person listed in the RFP.

14. **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf.

15. **Data and Safety Monitoring in Clinical Trials**

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trials be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers should refer to the Statement of Work for the solicitations specific requirements for data and safety monitoring.

The NIMH will evaluate the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis.

If the information provided about Data and Safety Monitoring is determined to be inadequate, you will be afforded the opportunity to further discuss and/or clarify your plan during discussions and in your Final Proposal Revision (FPR). If after discussions, the plan is considered inadequate, your proposal may not be considered further for award.

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Project Officer.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, FDA and NIH. The frequency of reporting of the conclusions of the monitoring activities should also be described in the plan. The overall elements of each plan may vary depending on the size and complexity of the trial. Examples of monitoring activities to be considered are described in the NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not98-084.html

The following provides further guidance for monitoring of phase I and II trials. This guidance does not take the place of the Institutional Review Board (RB) guidelines, Food and Drug Administration (FDA) requirements, or special NIH guidelines (e.g. NIH Guidelines for Research Involving Recombinant DNA Molecules).

For phase I and II clinical trials, investigators must submit a general description of the monitoring plan as part of the research application. This plan will be reviewed by the scientific review group and any comments or concerns will be included as an administrative note in the summary statement. In addition, before the trial begins, a detailed monitoring plan must also be included as part of the protocol, and submitted to NIMH and the local IRB. Oversight by NIMH staff must ensure that monitoring plans are in place for all phase I and II trials. At a minimum, all monitoring plans must include a description of the reporting mechanisms for serious and unexpected adverse events, as well as any other unanticipated problems involving risks to subjects or others, to the local IRB, the FDA (as appropriate), and those monitoring data and safety. Investigators must ensure that the NIMH Project Officer is informed of any actions taken by the IRB as a result of such adverse events. The decision for any NIMH action lies with the Institute Director.

The overall elements of the monitoring plan may vary depending on the potential risks, complexity, and nature of the trial. For multi-site phase III clinical trials, NIH requires the establishment of an independent DSMB. The DSMB should be composed of experts in scientific disciplines needed to interpret the data and ensure participant safety, or have these experts available if warranted. Other requirements are detailed in the NIH policy notice cited above. If the DSMB notes serious and unexpected adverse events, or any other unanticipated problems involving risks to subjects or others, related to the study, IRBs at all sites should be notified in a timely fashion. This can be done via a letter form the DSMB Chair/Administrator to the PI (or Coordinating Center) for distribution to local IRBs. This letter from the DSMB should also note whether serious adverse events (SAEs) were discussed, whether they appeared to be related to the trial, and whether the trial was approved to continue.

In phase I and II trials, a number of factors influence risk. A phase I trial or a new intervention (e.g., novel psychosocial treatment, drug or other somatic treatment) may involve increasing risk to a small number of participants as the intervention is escalated in intensity or dosage. For phase II trials, there is sometimes information about risks determined from pilot studies or work with normals, but risk may be increased as more participants are involved and the untoward effects may be confounded by the disease process. In clinical trials involving potentially high risks, special populations, blinded and/or multisite designs, investigators must consider additional monitoring and safeguards. Occasionally, phase I or II trials have established formal Data and Safety Monitoring Boards.

For many phase I and phase II trials, however, independent DSMBs may not be necessary or appropriate when the intervention is low risk. In most low risk, small-scale NIMH-supported studies, the Principal Investigator would be expected to perform the monitoring function as part of the general oversight and scientific leadership of the study. Such PIs must comply with prompt reporting of study-related toxicity and any unanticipated problems involving risks to subjects or others. In some instances, the study investigator or the IRB may determine that an independent individual may be needed for monitoring. In studies of small numbers of subjects, untoward effects may more readily become apparent through close monitoring of individual patients, while in larger studies risk may be assessed through statistical comparisons of treatment groups.

All institutions now carrying out an NIMH-funded multi-site phase I or II clinical trial must establish a data monitoring system (Central Reporting Entity – CRE). In accordance with 45 CFR part 46, serious and unexpected adverse events, as well as any other unanticipated problems involving risks to subjects or others, must be reported to the local IRB associated with the trial. If considered related to the trial, such events must also be reported to appropriate institutional officials and the Office for Human Research Projection (OHRP). In multi-site trials, one site may take on this latter responsibility, and report back to other PIs. Local investigators are to report SAEs to their IRB, and any Coordinating Center and/or CRE. If SAEs are considered related to the trial, then they must also be reported to IRBs at other participating sites.

The CRE for a particular trial will submit summary reports of the discussions of serious and unexpected adverse events (as well as any unanticipated problems involving risks to subjects or others) that are found to be related to the trial to the local IRBs associated with the trial, the NIMH Project Officer, the FDA (as appropriate) and OHRP. Each summary report should contain the following information:

A statement that review of data and outcomes (as appropriate) across all centers took place on a given date.

A summary of the review of the cumulative serious and unexpected adverse events (as well as any other unanticipated problems involving risks to subjects or others) that are related to the trial. This should include such events reported from all participating sites without specific disclosure by treatment arm, unless safety considerations require such disclosure.

The CRE recommendations for modification to the protocol

The frequency of summary reports to NIMH may depend on the nature of the trial. Additional NIH guidance regarding Data and Safety Monitoring and Reporting Adverse Events are found in the NIH Guide for Grants and Contracts Announcements at the following web sites: http://grants.nih.gov/grants/guide/notice-files/not99-107.html and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html.

16. **Research Patient Care Costs**

(a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.

(b) Patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine patient care costs. Patient care rates or amounts shall be established by the Secretary of HHS or his duly authorized representative.

(c) Prior to submitting an invoice for patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payers (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for patient care.

(d) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.

(e) Only those charges not recoverable from third party payers or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

17. SHARING RESEARCH DATA

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. this contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

H. BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal (Reference Form 2043 Attachment 5):

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.
10. DUNS number
11. EIN Number

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(3) Information Other than Cost or Pricing Data

a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

[Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.]

(4) **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. **Materials and services**.
Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.

(1) *Adequate Price Competition*. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).

(2) *All Other*. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of

your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

B. **Direct Labor**.
Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.

C. **Costs**
Indirect Costs.
Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

Other Costs.List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

D. **Royalties**.
If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

(1) Name and address of licensor.

(2) Date of license agreement.
(3) Patent numbers.
(4) Patent application serial numbers, or other basis on which the royalty is payable.
(5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
(6) Percentage or dollar rate of royalty per unit.
(7) Unit price of contract item.
(8) Number of units.
(9) Total dollar amount of royalties.
(10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

E. **Facilities Capital Cost of Money**.
When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)
(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

F. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Attachment 5). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at:

http://rcb.nci.nih.gov/forms/cpi.htm

G. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

H. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

**** ***(Please note that data substantiating the costs or prices proposed (i.e. payroll documentation, vendor quotes, invoice price, etc.) shall not be submitted with the initial proposal. This information will be requested from the offeror during the negotiation process. The initial proposal need only indicate from what source the proposed costs and prices are substantiated.)*** ****

I. **Reimbursement of Costs for Independent Research and Development Projects (Commercial Organizations Only)**

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

J. **Salary Rate Limitation in Fiscal Year 2003***

Beginning with the HHS Appropriations Act of Fiscal Year (FY) 1990, direct salary rate limitations have been placed on the NIH contracts that support the NIH Extramural R&D activities. Direct salary is exclusive of overhead, fringe benefits, and general and administrative expenses. The FY 2003 HHS Appropriations Act, P.L. 108-7 was enacted on February 20, 2003. This Act provides funding for the HHS for FY-03. In so providing, Division G, Title H, General Provisions, Section 204 of P.L.108-7 states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse and Mental Health Services Administration shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level I ($171,900)."

The salary rate ceiling applies to cost-reimbursement contracts that meet the definition above and to their subcontracts. It also applies to fixed-price level-of-effort, time and material, and labor hour contracts, where the Government's purpose is to buy the direct effort of an individual **and** the contract is for a project supporting the NIH Extramural R&D activities. It does not apply to fixed-price completion contracts. The rate limitation does not restrict the salary that an organization might pay an individual working under an NIH contract; it merely limits the portion of that salary that may be paid with Federal funds. Additionally, the rate limitation does not apply to fees paid to consultants.

(5) Other Administrative Data

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks,

office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

c) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments,

nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

(d). **Subcontractors**

If subcontractors are proposed, please include a complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

(e). **Travel Costs**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

I. "JUST IN TIME"

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information during the initial evaluation of proposals. Certain documents will not longer be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the travel policy, the annual financial statement, the total compensation plan, the subcontracting plan, and certain types of cost/pricing information will only be required to be submitted from those offerors included in the competitive range, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below:

A. Travel Policy.
The offeror's (and any proposed subcontractor's) written travel policy shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a travel policy as a part of their final proposal revision. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

B. Annual Report.
The offeror's most recent annual report shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a copy of their most recent annual report as a part of their final proposal revision.

C. Representations and Certifications
One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor. All offerors included in the competitive range will be required to submit a copy of Section K with their final proposal revision.

D. Total Compensation Plan. The offeror's total compensation plan shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a total compensation plan as a part of their final proposal revision.

INSTRUCTIONS

a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors [included in the competitive range will be required to/as a part of their business proposal] will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

EVALUATION

a) Total Compensation Plan (Professional Employees)

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

b) Cost (Professional Compensation)

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

c) Other (Labor Relations)

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

E. Small Business Subcontracting Plan.

The offeror's "Small Business Subcontracting Plan" shall **not** be submitted with the initial business proposal. Only those offerors included in the competitive range will be required to submit **an acceptable** subcontracting plan which will be incorporated as part of the contract upon award. The "Small Business Subcontracting Plan" is not to be confused with the "SDB Participation Plan" in attachment 3, item VII, which *is* submitted with the business proposal and evaluated before the CO sets the competitive range.

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the apparent successful offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment to this RFP is an example of such a plan.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing

of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and/or Service Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan.

F. Cost/Pricing Information.

The offeror's business proposal shall include the basic cost/pricing information specified in this RFP. In addition, the Government may require offerors included in the competitive range to submit additional information substantiating their proposed costs or prices. This additional cost/pricing information will be requested after establishment of the competitive range, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the contracting officer to evaluate the reasonableness of the price or to determine cost realism and financial responsibility. [The information may also include submission and certification of cost or pricing data.]

1. **General Instructions**

A. You must provide the following information on the first page of your pricing proposal:

(1) Solicitation, contract, and/or modification number;
(2) Name and address of offeror;
(3) Name and telephone number of point of contact;
(4) Name of contract administration office (if available);
(5) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
(6) Proposed cost; profit or fee; and total;
(7) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
(8) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
(9) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
(10) Date of submission; and
(11) Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal

any information reasonably required to explain your estimating process, including--

(1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
(2) The nature and amount of any contingencies included in the proposed price.

D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

G. Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body,

attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b)(1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

H. **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38**, (May 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

ATTACHMENT 5 TO STREAMLINED RFP No. NIMH-03-DM-0003

APPLICABLE RFP REFERENCES

A. The following general clauses and provisions are applicable to this specific RFP depending on your organizational status: Negotiated Cost-Reimbursement Contract with an Educational Institution, Negotiated Cost-Reimbursement Contract with a Non-Profit or, Negotiated Cost-Reimbursement Research and Development Contract. The clauses are located in the file "General Clauses" at URL: http://amb.nci.nih.gov/clauses/clauses.html .

B. The following items are applicable to this specific RFP and are located in the file entitled (except as noted) FORMS, FORMATS AND ATTACHMENTS at: http://ocm.od.nih.gov/contracts/rfps/Forms1.htm .

SUBMIT WITH TECHNICAL PROPOSAL (with original and every copy of technical proposal)

1. Technical Proposal Cover Sheet
2. Summary of Current and Proposed Activities
3. Technical Proposal Cost Information
4. Government Notice for Handling Proposals (as applicable)

SUBMIT WITH BUSINESS PROPOSAL:

1. Proposal Summary and Data record, NIH-2043, with every copy of business proposal.
2. Business Proposal Cost Information (Use form entitled “Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours” which is located at http://ocm.od.nih.gov/contracts/rfps/Forms1.htm .
3. Disclosure of Lobbying Activities, OMB SF-LLL, only one completed and signed original
4. Representations and Certifications - Negotiated Contract, only one completed and signed copy

OTHER - TO BE SUBMITTED LATER, “JUST IN TIME”:

1. Certificate of Current Cost or Pricing Data, NIH-1397, to be submitted with FPR, as required by the CO
2. DHHS Small, Small Disadvantaged, HUBZone and Women-Owned Small Business Subcontracting Plan, to be submitted as directed by the CO

ANTICIPATED TO BE INCLUDED AS CONTRACT ATTACHMENTS:

1. Invoice/Financing Requests Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1
2. NIH 2706, Financial Report of Individual Project/Contract, the form with instructions
3. Procurement of Certain Equipment, NIH(RC)-7
4. NIH Women and Minority Policy
5. Protection of Human Subjects Assurance/Identification/Certification/Declaration, OF310
6. NIH Policy for the Inclusion of Children as Participants In Research Involving Human Subjects

7. Research patient Care Costs, NIH(RC)-11
8. Annual Technical Progress Report Format for Each Study
9. NIH Policy for the Inclusion of Children as Participants in Research Involving Human Subjects.
10. Small Business Subcontracting, Form 294
11. NIMH Publication By-Lines

C. The Sample Contract Format for R&D Cost Reimbursement contracts is located in the file entitled, RFP FORMS, FORMATS AND ATTACHMENTS at http://ocm.od.nih.gov/contracts/rfps/Forms1.htm .

C. Supplemental information pertaining to Sections G, H and I of the Sample Contract Format include the following:

1. Section G, "Contract Administration Data" paragraph entitled "Invoice Submission" is amended to read as follows:

Invoice Submissions/Contract Financing Request

Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9. Invoice/financing requests shall be submitted as follows:

a. An original and two copies to the following designated billing office:

If hand-delivered or delivery Service	If using U.S. Postal Service
Contracting Officer Contracts Management Branch, ORM National Institute of Mental Health 6001 Executive Boulevard Room 8153 Rockville, Maryland 20852	Contracting Officer Contracts Management Branch, ORM National Institute of Mental Health 6001 Executive Boulevard Room 8153, MSC 9661 Bethesda, Maryland 20892-9603

Inquiries regarding payment of invoices should be directed to the designated billing office (301) 443-2696.

b. At a minimum, the Contractor agrees to include the following information on each invoice:

1. Contractor's name and invoice date,
2. NIMH's Contract number, or other authorization for delivery of property and/or services
3. Description, cost or price, and quantity of property and/or services actually delivered or rendered,
4. Shipping and payment terms,

5. Other substantiating documentation or information as required by the contract (see paragraph G.3.c, "NIMH Supplemental Billing Instructions" below,
6. Name where practicable, title, phone number, and complete mailing address of responsible official to whom payment is to be sent.

c. NIMH Supplemental Billing Instructions

1. The contractor agrees to provide, as applicable, a detailed breakdown on each invoice of the following cost categories:

(a) Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort, and amount claimed.
(b) Fringe Benefits - Cite rate and amount
(c) Overhead - Cite rate and amount
(d) Materials & Supplies - Include detailed breakdown.
(e) Travel - Identify travelers, dates, destination, purpose of trip, and amount. Cite COA, if appropriate.
(f) Consultant Fees - Identify individuals and amounts.
(g) Subcontracts - Attach subcontractor invoice(s). (Should be in same format and detail as required of the Prime Contractor.) Include COA Letter Number if applicable.
(h) Equipment - Cite authorization and amount.
(i) G&A - Cite rate and amount.
(j) Total Cost
(k) Fee (if applicable)
(l) Total Cost & Fee

Monthly invoices must include the cumulative total expended to date, adjusted (as applicable) to show any amounts suspended or disallowed by the Government.

2) The contractor agrees to immediately notify the contracting officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the amount allotted to the contract, and the reasons for the variance. Also refer to the requirements of the Limitation of Funds and Limitation of Cost Clauses in the contract.

2. Section G, "Contract Administration Data" the paragraph entitled "Post Award Evaluation of Contractor Performance" is amended to add:

Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web Site for review and comment by completing the registration form that can be obtained at the following address:

http://ocm.od.nih.gov/cdmp/cps_contractor.htm

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

3. Section H "Human Subject" is amended to read as follows:

Human Subjects

Research involving human subjects shall not be conducted under this contract until the final protocol has been approved by, both your local Internal Review Board (IRB) and the NIMH, written notice of such approval has been provided by the NIMH Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed Optional Form 310 certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, **provided** that it contains the information required by the Optional Form 310.

4. Section H "Required Education In The Protection Of Human Research Participants"

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. The information below is a summary of the NIH Policy Announcement:

The contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

5. Section H "Data And Safety Monitoring In Clinical Trials"

The contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

The contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.

Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

The Data and Safety Monitoring PLAN shall be established and approved prior to beginning the conduct of the clinical trial.

6. Section I Rights in Data, Patents, etc.

Section I of the resulting contract will contain the applicable "Patents, Data, and Copyrights, provisions and clauses for FAR Part 27 (FAR 52.227).

Attachment 6
PROPOSAL INTENT RESPONSE SHEET

RFP NIMH-03-DM-0003
PLEASE REVIEW THE ATTACHED RFP. FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE ON OR BEFORE **May 2, 2003**. YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL GREATLY ASSIST US IN PLANNING FOR PROPOSAL EVALUATION. CHECK ONLY ONE BOX.

☐ DO INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING:

_____

_____

☐ DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

_____

_____

_____

TYPED NAME AND TITLE:_____

INSTITUTION:_____

SIGNATURE:_____

TELEPHONE NO.:_____

EMAIL ADDRESS: _____

FAX NO. _____

DATE:_____

COLLABORATORS/CONSULTANTS - Provide name(s) and institution(s): (Continue list on additional pages if necessary)

_____

_____

_____

_____

RETURN TO: National Institute of Mental Health, NIH
Contracts Management Branch
Attn: Suzanne Stinson
Neuroscience Center Bldg., Rm. 8153
6001 Executive Blvd. (MSC 9661)
Bethesda, MD 20892-9603
FAX (301) 443-0501
ss704b@nih.gov

Attachment 7

PAST PERFORMANCE INFORMATION SURVEY QUESTIONNAIRE

FOR: **[IMPORTANT!! insert name of your company here before mailing to your customers!!]**

PLEASE RETURN COMPLETED SURVEY ASAP but no later than (IMPORTANT!!! insert date proposals are due) TO:

ATTN: SUZANNE STINSON
Contracting Officer
National Institute of Mental Health
Contract Management Branch
6001 Executive Blvd., Rm. 8153 (MSC 9661)
Bethesda, MD **20892**
(301)443-4116

PLEASE FILL IN THE FOLLOWING:

YOUR NAME: _____
YOUR AGENCY:_____
ADDRESS:_____
PHONE NUMBER:_____
FAX :_____
SIGNATURE OF PERSON COMPLETING SURVEY:_____
CONTRACT NUMBER/SOLICITATION NUMBER: _____

YOUR ROLE IN THIS CONTRACT -CIRCLE ONE

PROJECT OFFICER CONTRACTING OFFICER CONTRACT SPECIALIST

CONTRACT VALUE (INCLUDING OPTIONS): $_____
PERIOD OF PERFORMANCE (INCLUDING OPTIONS):_____
TYPE CONTRACT (I.E. COST REIMBURSEMENT, FIXED PRICE, ETC.):_____
APPROXIMATE PERCENTAGE OF WORK COMPETED BY SUBCONTRACTORS: ___ %
GENERAL DESCRIPTION OR TITLE OF CONTRACT: _____
_____

RATINGS Please answer each of the following questions with a rating that is based on objective measurable performance indicators to the maximum extent possible. Comments to support rating may be noted on last page.

NUMERICAL RATINGS ARE DEFINED AS FOLLOWS:

+2 EXCELLENT -Based on the Offeror's performance record, no doubt exists that the Offeror will successfully perform the required effort. A significant majority of sources of information are consistently firm instating that the Offeror's performance was superior and that they would unhesitatingly do business with the Offeror again.
+1 GOOD -Based on the Offeror's performance record, little doubt exists that the Offeror will successfully perform the required effort. Most sources of information state that the Offeror's performance was good, better that average, etc., that they would do business with the Offeror again.
0 None -No past performance history identifiable.
-1 MARGINAL -Based on the Offeror's performance record, some doubt exists that the Offeror will successfully perform the required effort. Many sources of information make unfavorable reports about the Offeror's performance and express concern about doing business with the Offeror again.
-2 POOR -Based on the Offeror's performance record, serious doubt exists that the Offeror will successfully perform the required effort. A significant majority of sources of information consistently stated that the Offeror's performance was entirely unsatisfactory and that they would not do business with the Offeror again.

PLEASE CIRCLE THE NUMERICAL SCORE INDICATING YOUR RATING

QUALITY OF SERVICE					
1. Compliance with contract requirements	+2	+1	0	-1	-2
2. Accuracy of reports	+2	+1	0	-1	-2
3. Effectiveness of personnel	+2	+1	0	-1	-2
4. Technical excellence	+2	+1	0	-1	-2
COST CONTROL					
1. Record of forecasting and controlling target costs	+2	+1	0	-1	-2
2. Current. Accurate and complete billings	+2	+1	0	-1	-2
3. Relationship of negotiated costs to actuals	+2	+1	0	-1	-2
4. Cost efficiencies	+2	+1	0	-1	-2
TIMELINESS OF PERFORMANCE					
1. Met interim milestones	+2	+1	0	-1	-2
2. Reliability	+2	+1	0	-1	-2
3. Responsive to technical direction	+2	+1	0	-1	-2
4. Completed on time including wrap up and contract administration	+2	+1	0	-1	-2
5. Met delivery schedules	+2	+1	0	-1	-2
6.Liquidated damage assessed: yes/no					
BUSINESS RELATIONS					
1. Effective management, including subcontracts	+2	+1	0	-1	-2
2. Reasonable/cooperative behavior	+2	+1	0	-1	-2
3. Responsive to contract requirements	+2	+1	0	-1	-2
4. Notification of problems	+2	+1	0	-1	-2
5. Flexibility	+2	+1	0	-1	-2
6. Pro-active vs. Reactive	+2	+1	0	-1	-2
7. Effective small/small disadvantaged business subcontracting program	+2	+1	0	-1	-2
CUSTOMER SATISFACTION					
1. The Contractor is committed to customer satisfaction	+2	+1	0	-1	-2
2. Would you recommend selection of this firm again?	+2	+1	0	-1	-2

ADDITIONAL COMMENTS:

(Your company letterhead here)

Date

Dear Client:

We are currently responding to the National Institute of Mental Health Solicitation No. _____, entitled _____. The Government is placing increased emphasis in its acquisition on past performance as a source selection factor and is requiring that clients of firms responding to solicitations be identified and their participation in the evaluation process be requested.

Therefore, enclosed is a past performance questionnaire for your completion. We are requesting that you complete the questionnaire and send it to the following address:

ATTN: Suzanne Stinson
Contracting Officer
National Institute of Mental Health
Contract Management Branch
6001 Executive Blvd., Rm. 8153 (MSC 9661)
Bethesda, MD **20892**
(301)443-4116

Since this information will be used as one of the evaluation factors for contract award, we are requesting that you complete this questionnaire and return it to the above address no later than _____(insert date proposals are due).

We thank you for your prompt response in this matter.

Sincerely,

(To be signed by Offeror)